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The International Index of Erectile Function (IIEF)—A Systematic Review of Measurement Properties



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ABSTRACT

Introduction: The International Index of Erectile Function (IIEF) is a patient-reported outcome measure to evaluate erectile dysfunction and other sexual problems in men.

Aim: To perform a systematic review of the measurement properties of the 15-item patient-reported outcome measure (IIEF-15) and the shortened 5-item version (IIEF-5).

Methods: A systematic search of scientific literature up to April 2018 was performed. Data were extracted and analyzed according to COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines for structural validity, internal consistency, reliability, measurement error, hypothesis testing for construct validity, and responsiveness. Evidence of measurement properties was categorized into sufficient, insufficient, inconsistent, or indeterminate, and quality of evidence as very high, high, moderate, or low.

Results: 40 studies were included. The evidence for criterion validity (of the Erectile Function subscale), and responsiveness of the IIEF-15 was sufficient (high quality), but inconsistent (moderate quality) for structural validity, internal consistency, construct validity, and test-retest reliability. Evidence for structural validity, test-retest reliability, construct validity, and criterion validity of the IIEF-5 was sufficient (moderate quality) but indeterminate for internal consistency, measurement error, and responsiveness.

Clinical Implications: Lack of evidence for and evidence not supporting some of the measurement properties of the IIEF-15 and IIEF-5 shows the importance of further research on the validity of these questionnaires in clinical research and clinical practice.

Strengths & Limitations: A strength of the current review is the use of predefined guidelines (COSMIN). A limitation of this review is the use of a precise rather than a sensitive search filter regarding measurement properties to identify studies to be included.

Conclusion: The IIEF requires more research on structural validity (IIEF-15), internal consistency (IIEF-15 and IIEF-5), construct validity (IIEF-15), measurement error (IIEF-15 and IIEF-5), and responsiveness (IIEF-5). The most pressing matter for future research is determining the unidimensionality of the IIEF-5 and the exact factor structure of the IIEF-15. **Neijenhuijs KI, Holtmaat K, Aaronson NK, et al. The International Index of Erectile Function (IIEF)—A Systematic Review of Measurement Properties. J Sex Med 2019;16:1078–1091.**

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Key Words: International Index of Erectile Function; Validity; Reliability; COSMIN; Measurement Properties

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INTRODUCTION

The International Index of Erectile Function (IIEF) is a widely used patient-reported outcome measure (PROM) to evaluate sexual problems in men.¹ The IIEF is a 15-item PROM (IIEF-15) including 5 domains: erectile function (6 items), orgasmic function (2 items), sexual desire (2 items), intercourse satisfaction (3 items), and overall satisfaction (2 items). Initial research revealed that the IIEF-15 had acceptable internal consistency ($\alpha > 0.70$) and test-retest reliability ($r > 0.70$), except for the orgasmic function scale.¹ Construct validity was good, and the IIEF-15 could detect changes before and after treatment.¹ A shortened 5-item version was developed to evaluate sexual problems in men by selecting the items that best discriminated between men with and without erectile dysfunction (ED) and adhered to the National Institutes of Health's definition of ED. The result was a 5-item version consisting of 4 items from the erectile function, and 1 item from the sexual intercourse satisfaction subscales. The IIEF-5 was able to discriminate clearly between patients with ED and those without.²

Information regarding validity and reliability is of importance for clinical research and practice. To be able to interpret the IIEF-15 and IIEF-5, we need to be certain that the subscales measure what they intend to measure, that they do so consistently, and (particularly for practice) what cutoff scores can be used to screen patients for ED. A review published in 2002 concluded that the IIEF was translated in 32 languages and adopted as a primary endpoint in >50 clinical trials worldwide.³ The authors reported that the IIEF-15 met the standard psychometric criteria for reliability and validity, had a high degree of sensitivity and specificity, and correlated well with other measures of treatment outcome. It also demonstrated good responsiveness.³

However, since then, many more studies have been published investigating the psychometric properties of the IIEF-15 and IIEF-5. Given the high frequency of use in both clinical practice and research, an update of the evidence on the psychometric properties of the IIEF-15 and IIEF-5 is warranted to investigate whether the initial results^{1–3} have been replicated in independent international and more recent validation studies. Therefore, the aim of this study was to perform a systematic review of the measurement properties of the IIEF-15 and IIEF-5.

In this review, we followed the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) methodology.⁴ This methodology is based on taxonomy and definitions of measurement properties for PROMs,⁵ including content validity, structural validity, internal consistency, cross-cultural validity, reliability, measurement error, criterion validity, hypotheses testing for construct validity, and responsiveness. We hypothesized that there would be evidence supporting sufficient psychometric values IIEF-15 and IIEF-5.

METHODS

Literature Search Strategy

The literature search was part of a larger systematic review (Prospero ID 42017057237), which investigated the measurement properties of 39 PROMs (including the IIEF-15 and IIEF-5) assessing the quality of life of cancer survivors included in an eHealth application called "Oncokompas".^{6–10} The databases Embase, Medline, and Web of Science were searched using the search terms of the PROM's name and acronyms, combined with a precise filter for measurement properties.¹⁰ The search was performed in January 2017. Appendix A contains the full search terms with regard to all 39 PROMs. Appendix B contains the search terms relating specifically to the IIEF. References were extracted from systematic reviews found in an earlier search of the larger systematic review, and added to the search results. A search update was performed in April 2018. Due to the limitation of the sensitivity of the precise filter (93% sensitive),¹⁰ a manual search using rudimentary search filters was performed in Google Scholar and PubMed to check for any prominent records missed in the search update.

Inclusion and Exclusion Criteria

Studies were included that reported original data on ≥ 1 of the following measurement properties of the IIEF as defined by the COSMIN taxonomy^{5,11,12}: structural validity (whether the hypothesized measurement model is confirmed), internal consistency (the degree of interrelatedness among the items of the measure), reliability (the proportion of total variance between multiple measurements, which is due to "true" differences between measurements), measurement error (a measure of systematic and random error in change scores), criterion validity (whether the measure is an adequate reflection of a gold standard; in the case of the IIEF this is most often a diagnosis of ED), cross-cultural validity (whether the test can be interpreted similarly in different cultures), responsiveness (whether the measure is capable of measuring change over time in the construct to be measured), and hypothesis testing for construct validity (whether the test measures the construct it proposes to measure), which consists of known-groups comparison (a comparison between groups known to have differences on the construct), convergent validity (correlations with other measures that should be related), and divergent validity (correlations with other measures that should be unrelated). Although of importance for establishing validity, content validity was not investigated because it was beyond the scope of the current review. Validation studies focused on other PROMs, and non-validation studies that used the IIEF that also reported evidence on the measurement properties of the IIEF were included.

Studies that were only available as abstracts or conference proceedings were excluded, as well as non-English publications. Titles and abstracts, and the selected full-texts were screened by 2 independent reviewers (K.N. & M.V./K.H.). Disagreements were discussed until consensus was reached.

Data Extraction

Data on each of the measurement properties was extracted by two independent researchers (K.N. & A.vdH./H.M./E.V./K.H.). Relevant data included the type of measurement property, its result, and information on methodology. Disagreements were discussed until consensus was reached.

Data Analysis

Data analysis was performed in 3 consecutive steps. First, the methodologic quality of the included studies was rated using the 4-point scoring system of the COSMIN checklist.¹³ Methodologic aspects regarding design requirements and preferred statistical methods specific to each measurement property under consideration, were rated as either “inadequate,” “doubtful,” “adequate,” or “very good.” The methodologic quality was summarized per measurement property per study as the lowest score received on any of the methodologic aspects. [Appendix C](#) contains the final study quality ratings.

Second, each measurement property in each individual study was rated as sufficient, insufficient or indeterminate, following the COSMIN guidelines for systematic reviews of PROMs.⁴ These ratings were qualitatively summarized to determine the overall rating of the measurement property for the IIEF. If all studies indicated a “sufficient,” “insufficient,” or “indeterminate” rating for a specific measurement property, the overall rating of this measurement property was rated accordingly. If there were inconsistencies between studies, explanations were explored (eg, differences in methodologic quality, differences in population, etc). If explanations were found, they were discussed until consensus was reached regarding the overall rating of the measurement property. If no explanations were found, the overall rating would be inconsistent.

Third, the overall rating of evidence per measurement property was supplemented by a level of quality of the evidence, using a modified Grading of Recommendations Assessment, Development and Evaluation approach from the COSMIN methodology.⁴ This approach takes into account (i) study quality, (ii) directness of evidence, (iii) inconsistency of results, and (iv) precision of evidence (number of studies and sample size). The overall quality of evidence was rated as high, moderate, low, or very low. Measurement properties that were rated as indeterminate in the previous step did not receive a rating, as there was no evidence to rate.

All ratings (methodologic quality, measurement property rating, and Grading of Recommendations Assessment, Development and Evaluation rating) were rated by 2 independent researchers (K.N. & K.H.). Discrepancies in ratings were discussed until consensus was reached.

RESULTS

Search Results

The initial search identified 1,401 non-duplicate abstracts of which 568 were relevant to the IIEF ([Supplementary Figure 1](#)). A total of 526 abstracts and 17 full texts were excluded because

they did not provide unique information on a measurement property. The search update up to April 2018 identified 342 more non-duplicate abstracts. A total of 317 abstracts and 17 full texts were excluded because they did not provide unique information on a measurement property of the IIEF. 10 references were found through manual means, of which 5 were excluded during abstract screening because they did not provide unique information on a measurement property of the IIEF.

In total, we included 40 articles: 31 on the IIEF-15,^{1,14–43} 7 on the IIEF-5,^{2,44–49} and 2 on both the IIEF-15 and IIEF-5.^{50,51} An overview of study characteristics is provided in [Table 1](#). Studies reported sample sizes ranging from 40 to 1,764, and 12 different countries were reported: Turkey (Turkish), Spain (Spanish), Taiwan (Taiwanese Mandarin/Hokkien), Germany (German), Iran (Persian), Italy (Italian), Malaysia (Malay), Portugal (Portuguese), China (Chinese), Canada (French), Pakistan (Urdu), and the Netherlands (Dutch). Other included studies likely have been conducted in other countries, but the nationality of participants was not always clearly specified. The combined body of the 33 studies on the IIEF-15 and the 9 studies on the IIEF-5 reported on all measurement properties, except cross-cultural validity.

Structural Validity

8 studies reported on structural validity of the IIEF-15,^{1,17,22,26,28,36,43,51} of which 1 study³⁶ reported 2 types of analyses ([Table 2](#)). Methodologic quality was rated as “very good”,^{17,28} “adequate”,^{1,22,43,51} or “doubtful”.^{26,36} 1 “doubtful” score was due to an insufficient sample size (“other flaws” in COSMIN methodologic quality),²⁶ whereas the other was because of very unequal subgroup sizes (“other flaws” in COSMIN methodologic quality).³⁶

3 studies of “very good”^{17,28} and “doubtful”³⁶ quality reported confirmatory factor analyses (CFAs). The evidence on structural validity was rated as sufficient in 2 studies, because a good fit was found for a 5-factor structure.^{28,36} The evidence was rated as insufficient for the third study, because the fit for the 5-factor structure was below acceptable levels (Comparative Fit Index [CFI] < 0.95).¹⁷ The evidence was rated as indeterminate for 6 studies of the IIEF-15, of “adequate”^{1,22,43,51} and “doubtful”^{26,36} quality, because they reported principal component analyses (PCAs) without fit measures. Notably, 2 of these studies reproduced the hypothesized 5 components, 2 studies found 4 components, and 2 studies found 2 components.

1 study reported on structural validity of the IIEF-5⁴⁶ ([Table 2](#)). Methodologic quality was rated as “very good.” Evidence on structural validity was rated as sufficient, because a good fit of a Rasch model was reported.

Internal Consistency

15 studies reported on internal consistency of the IIEF-15^{1,15,16,22,26,28,31,34–36,38,41,43,50,51} ([Supplementary Table 1](#)). Methodologic quality of these studies was rated as “very

Table 1. Characteristics of included studies

Reference	Population	Sample size	Main aim of study
IIEF-15			
Althof et al ¹⁴	Patients with ED with somewhat low self-esteem	282	Investigate the impact of sildenafil treatment on psychosocial functioning and well-being in men with ED from 4 countries
Bayraktar et al ¹⁵	Patients with ED	225	Assess the reliability of the physician-assisted IIEF-15 (Turkish version) in patients with ED
Bayraktar et al ¹⁶	Patients with ED	458	To analyze the impact of assistance on the comprehensibility and reliability of the Turkish version of the IIEF-15 questionnaire
Bushmakina et al ¹⁷	Patients with ED enrolled in a RCT on sildenafil	500	Testing structural validity of IIEF-15
Cappelleri et al ¹⁸	111 ED patients in RCT on sildenafil; 109 control patients; 37 ED patients; and 21 age-matched controls	278	Development and validation of IIEF-15
Cappalleri et al ¹⁹	Patients with ED enrolled in a RCT on sildenafil	247	Examine the relationship between patients' self-assessment of EF and the EF domain of the IIEF with respect to ED severity
Cappalleri et al ²⁰	Patients with ED enrolled in a RCT on sildenafil	209	Mapping the relationship among 4 categories of the EHS and the IIEF-EF, QE-Q, SEX-Q, and SEAR
O'Leary et al ²¹	Patients with ED enrolled in a RCT on sildenafil with somewhat low self-esteem	244	Assess the change in confidence, relationship satisfaction and self-esteem in men with ED treated with sildenafil
Coyne et al ²²	HIV-positive males who have sex with men	486	Validate an adapted version of IIEF-15 for use in HIV-positive men who have sex with men
Flynn et al ²³	Cancer patients	389	Validation of the PROMIS sexual function and satisfaction scales
García-Cruz et al ²⁴	Patients referred from general practitioners to urologic practice	125	Validate Erection Hardness Score in Spanish
Gelhorn et al ²⁵	Patients diagnosed with hypogonadism	177	Validate the Hypogonadism Impact of Symptoms Questionnaire Short Form
González et al ²⁶	Patients participating in a cardiopulmonary or metabolic rehabilitation program	78	Validate the IIEF-15 in Portuguese (Brazil) in patients with cardiopulmonary and metabolic diseases
Hwang et al ²⁷	Males aged >30	1060	Assess prevalence of erectile dysfunction in Taiwan
Kriston et al ²⁸	Patients with cardiovascular diseases in rehabilitation centers	261	Test 4 proposed factor structures of the IIEF-15 in German population
Maasoumi et al ²⁹	Males working in four different work settings	181	Validate the Sexual Quality of Life—Male in Persian (Iran)
Mulhall et al ³⁰	190 men screened for ED ; 902 males participating in a community health survey	1259	Development of Sexual Experience Questionnaire
Nimbi et al ³¹	Convenience sample	425	Validate the Sexual Modes Questionnaire in Italian
O'Toole ³²	Patients with inflammatory bowel disease	175	Develop a IBD-specific Male Sexual Dysfunction Scale
Parisot et al ³³	Patients with localized prostate cancer who underwent surgery	75	Validation and responsiveness of Erection Hardness Score
Pascoal et al ³⁴	Heterosexual males in a dyadic relationship	129	Development of the Beliefs About Sexual Functioning Scale
Quek et al ³⁵	20 patients admitted for transurethral resection of the prostate and 20 control males	40	Validate the IIEF-15 in Malaysia
Quinta Gomes et al ³⁶	Sexually healthy males and patients with ED	1363	Validate the IIEF-15 in Portugal

(continued)

Table 1. Continued

Reference	Population	Sample size	Main aim of study
Rosen et al ¹	111 patients with ED part of a sildenafil RCT; 109 matched healthy men; 37 patients with ED; 21 matched healthy controls	278	Development and first validation of IIEF-15
Rosen et al ³⁷	Participants in RCT on tadalafil	863	Estimate Minimal Clinically Important Difference for the Erectile Function subscale of the IIEF-15
Rubio-Aurioles et al ³⁸	51 couples with untreated ED; 57 couples without ED	107	Development and first validation of the Female Assessment of Male Erectile
Saffari et al ³⁹	Males attending a health post	1764	Validate the Male Genital Self-Image Scale for Iranian Men
Serefoglu et al ⁴⁰	Patients from an urology clinic	430	Analyze the impact of patient age, education level, and household income on the comprehension of the IIEF-15 (Turkish version) and determine the patient characteristics that make this questionnaire less reliable
Tang et al ⁴¹	260 patients diagnosed with premature ejaculation, and 104 healthy controls	364	Validate the Premature Ejaculation Diagnostic Tool in Chinese
Terrier et al ⁴²	Sexually active patients with early-stage prostate cancer after radical prostatectomy	178	Define the optimal Erectile Functioning score that optimally defines “functional” erections after radical prostatectomy
Wiltink et al ⁴³	59 ED patients, 38 patients with Peyronie’s disease, and 33 control males	130	Validate IIEF-15 for the German population (Germany)
IIEF-15 & IIEF-5			
Dargis et al ⁵⁰	Canadian males aged > 65 years	508	Validation of IIEF-15 and IIEF-5 in an older population
Lim et al ⁵¹	111 healthy males; 60 patients attending primary care clinics; 32 ED patients undergoing sildenafil therapy	197	Validate the IIEF-15 and IIEF-5 in Malay (Malaysia)
IIEF-5			
Aslan et al ⁴⁴	Patients with ED	81	Evaluate the association between IIEF-5 and Erection Hardness Grade Score in patients who underwent sildenafil citrate treatment for ED
Cappelleri et al ⁴⁵	Patients with ED enrolled in a RCT on sildenafil	247	Examine the relationship between patients’ self-assessment of EF and classification of ED severity using the IIEF-5
Lin et al ⁴⁶	Prostate cancer patients in sexual relationships	1058	Rasch analysis of Premature Ejaculation Diagnostic Tool and IIEF-5 in Iranian prostate cancer patients
Mahmood et al ⁴⁷	Patients from an urology clinic	47	Validate the IIEF-5 in Urdu (Pakistan)
Rosen et al ²	1063 patients with ED enrolled in a sildenafil RCT, and 116 healthy controls	1152	Development of an abridged version of the IIEF-15 (the IIEF-5)
Tang et al ⁴⁸	Patients diagnosed with LPE, heterosexual with a sexual relationship >6 months	406	Validate IIEF-5 for erectile function in Lifelong Premature Ejaculation patients in China
Utomo et al ⁴⁹	82 ED patients; 253 controls	335	Validate IIEF-5 in Dutch (Netherlands)

ED = erectile dysfunction; EF = erectile function; EHS = Erection Hardness Score; IBD = inflammatory bowel disease; IIEF = International Index of Erectile Function; LPE = lifelong premature ejaculation; PROMIS = Patient-Reported Outcomes Measurement Information System; QEQ = Quality of Erection Questionnaire; RCT = randomized controlled trial; SEAR = Self-Esteem And Relationship questionnaire; SEX-Q = Sexual Experience Questionnaire.

good”,^{1,16,22,28,36,38,50,51} “adequate”,^{26,31,43} or “inadequate”.^{16,34,35,41} The inadequate scores were due to only reporting internal consistency for the total IIEF-15 instead of its subscales^{16,34,41} or because of a very small sample size (“other flaws” in COSMIN methodological quality).³⁵

8 studies, of “very good”,^{15,28,36,50} “adequate”,³¹ and “inadequate”^{34,35,41} quality, reported Cronbach’s α of sufficient values of the IIEF-15. 5 studies, of “very good”^{1,22,38,51} and “adequate”²⁶ quality, reported Cronbach’s α of insufficient values of the IIEF-15. In 2 studies, the evidence on internal

Table 2. Structural validity

Reference	Methodology	Outcome	Rating	Quality
IIEF-15				
Bushmakin et al ¹⁷	Confirmatory factor analysis	5-factor solution found on baseline (N = 500; CFI = .92); on end of DBPC phase (N = 458; CFI = .94); and end of open-label (N = 454; CFI = .93), all with bad fit (CFI < .95).	Insufficient	Very good
Coyne et al ²²	Principal component analysis	Four factors with Eigenvalue > 1.5. The original domains of intercourse and overall satisfaction appeared together in 1 factor.	Indeterminate	Adequate
González et al ²⁶	Principal component analysis	5 factors explaining 75.8% of variance; most questions were loaded correctly on their respective domains, except for sexual satisfaction domain, which comprises questions 6, 7, and 8, which presented a confounding factor. Question 1 equally loaded on 2 factors.	Indeterminate	Doubtful*
Kriston et al ²⁸	Confirmatory factor analysis	Original 5-factor model had acceptable fit (GFI = .889; TLI = .933; CFI = .949; SRMR = .045; RMSEA = .09) as did a 4-factor model (GFI = .849; TLI = .908; CFI = .926; SRMR = .049; RMSEA = .107). A 2-factor model had non-acceptable fit (CFI = .783; TLI = .854; CFI = .876; SRMR = .064; RMSEA = .134), as did a 1-factor model (GFI = .743; TLI = .812; CFI = .839; SRMR = .072; RMSEA = .152). CAIC favored the original 5-factor model (512.68).	Sufficient	Very good
Lim et al ⁵¹	Principal component analysis	The expected structure of 5 distinct domains was not clearly present. The eigenvalue was concentrated on the first factor, whereas the remaining 4 factors extracted had eigenvalue <1. Factor 2 of the Malay version of IIEF corresponded with the OS domain of the original IIEF, whereas factor 3 corresponded with SD domain, and factor 4 with OF domain. Factor 1 contained a mixture of loadings from both EF and IS domains.	Indeterminate	Adequate
Quinta Gomes et al ³⁶	Principal component analysis	2 components explaining 55% variance. The first component cluster loadings from 8 items of the erection and orgasm domains of the original IIEF. The second component included the original dimensions of SD, IS, and OS, was composed of the remaining 6 items of the scale.	Indeterminate	Doubtful [†]
Quinta Gomes et al ³⁶	Confirmatory factor analysis	Acceptable fit for 2-factor model (RMSEA = .077; CFI = .94; GFI = .93; AGFI = .90) and 5-factor model (RMSERA = .067; CFI = .96; GFI = .95; AGFI = .92)	Sufficient	Doubtful
Rosen et al ¹	Principal component analysis	Five factor solution. (1) erectile function, (2) orgasmic function, (3) sexual desire, (4) intercourse satisfaction, and (5) overall satisfaction.	Indeterminate	Adequate
Wiltink et al ⁴³	Principal component analysis	2 factors found explaining 70% variance. First factor (12 items) of sexual function. Second factor (3 items) of sexual desire.	Indeterminate	Adequate
IIEF-5				
Lin et al ⁴⁶	Rasch analysis	Monotonical increase across IIEF; 1 local dependency in IIEF; no substantial DIF in IIEF	Sufficient	Very good

CFI = Comparative Fit Index; EF = erectile function; GFI = Goodness of Fit Index; IIEF = International Index of Erectile Function; IS = intercourse satisfaction; OF = orgasmic function; OS = overall satisfaction; RMSEA = Root Mean Square Error of Approximation; SD = sexual desire; SRMR = standardized root mean square residual; TLI = Tucker Lewis Index.

*Due to insufficient sample size.

[†]Due to very unequal subgroup sizes.

consistency was rated as indeterminate because it could not be interpreted: 1 study did not report the internal consistency per subscale,¹⁶ and 1 study reported internal consistency for 2 subscales, resulting from their PCA results.⁴³

5 studies reported on internal consistency of the IIEF-5^{47–51} (Supplementary Table 1). Methodologic quality of these studies was rated as “very good”^{48–51} or “inadequate”.⁴⁷ The inadequate score was due to a very small number (“other flaws” in COSMIN methodologic quality).⁴⁷ The evidence of internal consistency was rated as indeterminate for all 5 studies, because unidimensionality was not investigated (see Structural Validity), which is a prerequisite for internal consistency.

Test-Retest Reliability

8 studies reported on test-retest reliability of the IIEF-15^{1,15,16,35,36,40,51} (Table 3). Methodologic quality of these studies was rated as “doubtful”,^{1,16,26,36,40,51} or “inadequate”.^{15,35} The doubtful scores were due to inappropriate time intervals (the same day)^{40,51} and reporting of correlation coefficients instead of the intraclass correlation coefficient.^{1,16,36,40} The inadequate scores were due to test conditions that differed across measurements,¹⁵ and a very small number (“other flaws” in COSMIN methodologic quality).³⁵

The evidence on test-retest reliability was rated as sufficient in 5 studies, of “doubtful”^{1,26,51} and “inadequate”^{15,35} quality. The evidence was rated as insufficient in 2 studies, of “doubtful”^{36,40} quality, because reported values of reliability were <0.70 . The evidence was rated as indeterminate in 1 study, of “doubtful”¹⁶ quality, because the values were subdivided in 6 subgroups and not well interpretable.

2 studies reported on test-retest reliability of the IIEF-5.^{49,51} Methodologic quality was rated as “adequate”⁴⁹ or “doubtful”.⁵¹ The doubtful score was due to inappropriate time intervals (the same day).⁵¹ The evidence on test-retest reliability in both studies was rated as sufficient.

Measurement Error

1 study reported measurement error of IIEF-15,³⁵ and measurement error was calculated for 1 study that reported test-retest reliability¹ (Supplementary Table 2). Methodologic quality was rated as “adequate”¹ or “inadequate”.³⁵ The inadequate rating was due to a very small number (“other flaws” in COSMIN methodologic quality).³⁵

For interpretation of measurement error, the minimal clinically important difference (MCID) is necessary. The evidence on measurement error was rated as indeterminate for the 2 studies^{1,35} because no MCID was reported for any of the subscales in any of the included studies, except for the erectile function subscale for which a MCID was reported (mean MCID = 7.27).³⁷

The evidence on measurement error of the erectile function subscale was rated as insufficient for 1 study,³⁵ for which we

could calculate the standard error of measurement (0.69–3.59) and the smallest detectable change (SDC; 1.90–9.94). The SDC is the minimum change score necessary to have 95% confidence that it represents a true change. The MCID is the smallest change score that represents a clinically relevant change. The SDC should be smaller than the MCID, so that a smallest clinically relevant change score can be distinguished from measurement error. In this case, the SDC (9.49) was larger than the MCID (7.27), leading to an insufficient rating for the erectile function subscale.

1 study reported measurement error of the IIEF-5.⁴⁹ Methodologic quality was rated as “adequate.” Limits of agreement (LoA) were reported (10.1). Evidence on measurement error was rated as indeterminate, because no MCID or MIC was reported.

Construct Validity (Hypothesis Testing)

7 studies reported known-group comparison of the IIEF-15^{1,35,36,41,43,50,51} (Supplementary Table 3). Known group differences were investigated in relation to age,⁵⁰ diagnosis of ED^{1,36,43,51}, diagnosis of premature ejaculation,⁴¹ lifelong vs acquired premature ejaculation,⁴¹ and treatment vs control.³⁵ The methodologic quality was rated as “adequate”^{1,36,41,43,50,51} or “inadequate”.³⁵ The inadequate rating was due to a very small number (“other flaws” in COSMIN methodologic quality).³⁵ Evidence for construct validity was rated as sufficient for all studies.

2 studies reported known-group comparison of the IIEF-5^{2,50} and compared age groups⁵⁰ and diagnosis of ED.² The methodologic quality was rated as “adequate”⁵⁰ or “doubtful”.² The doubtful rating was due to very unequal group sizes (“other flaws” in COSMIN methodologic quality).² Evidence of construct validity was rated as sufficient.

Convergent Validity

17 studies reported on convergent validity of the IIEF-15^{1,19,20,23–25,27,29–34,38,39,41,43} (Supplementary Table 4). The IIEF-15 was compared with a single-item self-assessment of ED,¹⁹ the Patient Reported Outcomes Measurement Information System,²³ Quality Erection Questionnaire,²⁷ Erection Hardness Score,^{20,24,27,33} Sexual Experience Questionnaire,³⁰ Male Genital Self-Image Scale,³⁹ Female Assessment of Male Erection,³⁸ partnership satisfaction,⁴³ Hypogonadism Impact of Symptoms Questionnaire Short Form,²⁵ Sexual Quality of Life—Male,²⁹ Sexual Modes Questionnaire,³¹ Inflammatory Bowel Disease Male Sexual Dysfunction Scale,³² Beliefs About Sexual Functioning Scale,³⁴ Premature Ejaculation Tool,⁴¹ and clinician ratings.^{1,38,43}

The methodologic quality was rated as “adequate”^{1,23,27,29,31,32,34,38,39,41,43} or “doubtful”.^{19,20,24,25,33} The doubtful ratings were due to a small number (“other flaws” in COSMIN methodologic quality),³³ use of the Pearson correlation where the Spearman correlation should have been

Table 3. Test-retest reliability

Reference	Coefficient	IIEF-5	Total score	EF	OF	SD	IS	OS	Rating	Quality
IIEF-15										
Bayraktar et al ¹⁵	Correlation		.91	.94	.83	.87	.75	.78	Sufficient	Inadequate*
Bayraktar et al ¹⁶	Rho		.39–.87						Indeterminate	Doubtful†
González et al ²⁶	ICC		.80–.98	.90–.98	.91–.98	.80–.92	.82–.97	.89–.98	Sufficient	Doubtful
Quek et al ³⁵	ICC			.77	.75	.87	.79	.85	Sufficient	Inadequate‡
Quinta Gomes et al ³⁶	Correlation			.55	.69	.14	.71	.90	Insufficient	Doubtful†
Rosen et al ⁴⁰	Correlation		.82	.84	.64	.71	.81	.77	Sufficient	Doubtful†
Serefoglu et al ⁴⁰	Kappa		.37						Insufficient	Doubtful*
IIEF-15 & IIEF-5										
Lim et al ⁵¹	ICC		.92	.88	.82	.82	.89	.82	Sufficient	Doubtful ⁵
IIEF-5										
Utomo et al ⁴⁹	ICC								Sufficient	Adequate

EF = Erectile Function; IIEF = International Index of Erectile Function; IS = intercourse satisfaction; OF = orgasmic function; OS = overall satisfaction; SD = sexual desire.

*Due to test conditions differing across measurements.

†Due to reporting of inappropriate coefficients.

‡Due to an extremely small number.

⁵Due to inappropriate time intervals.

used,²⁴ imprecise reporting of hypotheses (“other flaws” in COSMIN methodologic quality),²⁵ the lack of information on measurement properties of the comparator instrument,¹⁹ or imprecise reporting of results.²⁰

The evidence on construct validity was rated as sufficient for 11 studies, of “adequate”^{1,23,27,29,30,38,43} and “doubtful”^{19,24,25,33} quality. The evidence was rated as insufficient for 5 studies of “adequate”^{31,32,34,39,41} and 1 study of “doubtful”²⁰ quality, because reported correlations were low.

2 studies reported on convergent validity of the IIEF-5,^{44,45} and compared the IIEF-5 to the Erection Hardness Scale,⁴⁴ a single-item self-assessment of ED,⁴⁵ the Erectile Dysfunction Inventory of Treatment Satisfaction,⁴⁵ a 5-item version of the Erectile Dysfunction Inventory of Treatment Satisfaction filled in by a partner,⁴⁵ and a single item of global efficacy of erections.⁴⁵ Methodologic quality was rated as “adequate”⁴⁴ or “doubtful”.⁴⁵ The doubtful rating was due to the lack of information on measurement properties of the comparator instrument.⁴⁵ The evidence on construct validity was rated as sufficient for 1 study⁴⁴ and insufficient for 1 study,⁴⁵ because the reported correlation was low.

Divergent Validity

3 studies reported on divergent validity of the IIEF-15^{1,43,50} (Supplementary Table 5) and compared the IIEF-15 to the Dyadic Adjustment Test and SF-12,⁵⁰ the Locke-Wallace Marital Adjustment Test,¹ State-Trait Anxiety Inventory, Center for Epidemiological Studies Depression Scale,⁴³ and social desirability.^{1,43} Methodologic quality was rated as “adequate”^{43,50} or “doubtful”.¹ The doubtful score was due to non-reporting of measurement properties of the comparison instrument. The evidence on construct validity was rated as sufficient for all studies.

1 study reported on divergent validity of the IIEF-5⁵⁰ (Supplementary Table 5) and compared the IIEF-5 to the Dyadic Adjustment Test and SF-12. Methodologic quality was rated as “adequate,” and evidence was rated as sufficient.

Criterion Validity

4 studies reported on criterion validity of the IIEF-15 Erectile Function subscale^{18,38,42,43} (Table 4). 1 study also reported criterion validity for the IIEF-15 total score.⁴³ Methodologic quality was “very good”,^{18,38} “adequate”,⁴³ or “doubtful”.⁴² The “doubtful” rating was due to use of a questionable gold standard (intercourse satisfaction). All other studies used ED diagnosis as the gold standard.

The evidence on criterion validity was rated as sufficient for 3 studies of “very good”^{18,38} and “doubtful”⁴² quality. 2 studies^{18,38} reported area under the curve (AUC) values for the erectile function subscale as 0.97 for diagnosing ED, with good sensitivity (0.97–0.98) and specificity (0.79–0.88) for the cut-off point of 25. 1 study⁴² reported an AUC value for the erectile

Table 4. Criterion validity

Reference	Instrument	AUC	Cutoff	Sensitivity	Specificity	PPV	NPV	Rating	Quality
IIEF-15									
Cappelleri et al ¹⁸	IIEF-15 EF	.97	25	.97	.88	.89	.97	Sufficient	Very good
Rubio-Aurioles et al ³⁸	IIEF-15 EF	.97	25	.98	.79			Sufficient	Very good
Terrier et al ⁴²	IIEF-15 EF	.86	24	.78	.80			Sufficient	Doubtful*
			25	.77	.82				
Wiltink et al ⁴³	IIEF-15 Total		53	.87	.75	.85		Indeterminate	Adequate
	IIEF-15 EF		21	.84	.72	.84			
IIEF-5									
Lim et al ⁵¹	IIEF-5	.86	17	.85	.75			Sufficient	Adequate
Rosen et al ²	IIEF-5	.97	21	.98	.88	.89	.98	Sufficient	Doubtful†
Tang et al ⁴⁸	IIEF-5	.97	22	1.00	.06			Sufficient	Very good
			15.5	.97	.86				

AUC = area under the curve; CART = Classification and Regression Trees; IIEF = International Index of Erectile Function; NPV = negative predictive value; PPV = positive predictive value.

*Due to a doubtful criterion.

†Due to very unequal group sizes which biases the results of the CART algorithm; and due to usage of training sample in cross-validation.

function subscale as 0.86 for determining intercourse satisfaction. Good sensitivity (0.77 and 0.78) and specificity (0.92 and 0.80) were reported for the cutoff points of 24 and 25, respectively. The evidence was rated as indeterminate for 1 study,⁴³ because no AUC value was reported.

3 studies reported on criterion validity of the IIEF-5^{2,48,51} (Table 4). Methodologic quality was “very good”,⁴⁸ “adequate”,⁵¹ or “doubtful”.² The doubtful rating was due to very unequal group sizes.² The evidence on criterion validity was rated as sufficient for all studies, with reported AUC between 0.86–0.97.^{2,48,51} All studies reported good sensitivity (0.85–0.98) and specificity (0.75–0.88) for cutoff points of 15.5, 17, and 21.

Responsiveness

6 studies reported responsiveness of the IIEF-15^{1,14,19,21,33,35} (Supplementary Table 6). Methodologic quality was rated as “adequate”,^{1,14,19,21,33} or “inadequate”.³⁵ The inadequate rating was due to a very small number (“other flaws” in COSMIN methodologic quality).³⁵ The evidence on responsiveness was rated as sufficient for all 6 studies.

2 studies reported on responsiveness of the IIEF-5^{45,49} (Supplementary Table 6). Methodologic quality was rated as “adequate”⁴⁵ or “doubtful”.⁴⁹ The doubtful rating was due to a very small group of treated patients (“other flaws” in COSMIN methodologic quality). The evidence on responsiveness was rated as sufficient for both studies.

Data Synthesis

The overall ratings of the measurement properties can be found in Table 5. Structural validity of the IIEF-15 was rated as inconsistent with evidence of moderate quality, due to the inconsistencies in the findings. Structural validity of the IIEF-5 was

rated as sufficient with evidence of moderate quality, because it was based on only 1 study.

Internal consistency of the IIEF-15 was rated as inconsistent with evidence of moderate quality because of inconsistencies in the findings. Internal consistency of the IIEF-5 was rated as indeterminate, because of the lack of evidence for unidimensionality.

Reliability of the IIEF-15 was rated as inconsistent with evidence of moderate quality, due to inconsistencies in the findings. Reliability of the IIEF-5 was rated as sufficient with evidence of moderate quality, due to some risk of bias resulting from the methodologic quality. For both IIEF-15 and IIEF-5, measurement error was rated indeterminate, except for the erectile function scale, which was rated as insufficient.

Construct validity (hypothesis testing) of the IIEF-15 was rated as inconsistent with evidence of moderate quality. 11 studies showed sufficient scores, whereas 6 studies showed insufficient scores. We note that some of the comparator instruments in convergent validity are of questionable relevance (eg, the Male Genital Self-Image Scale) or quality (eg, comparators that were only validated once in their lifetime). As such, while formally rating the construct validity of the IIEF-15 as inconsistent, the rating leans more to sufficient than insufficient. Construct validity of the IIEF-5 was rated as sufficient with evidence of high quality. 1 study showed values of insufficient convergent validity of the IIEF-5, these values were only just below sufficient levels and were discounted against the evidence for sufficient construct validity.

Criterion validity was rated as sufficient and evidence of high quality for the IIEF-15, and evidence of moderate quality for the IIEF-5 due to some risk of bias resulting from the methodologic quality. Responsiveness was rated as sufficient and evidence of high evidence for the IIEF-15 and as indeterminate for the IIEF-5.

Table 5. Ratings of measurement properties

Measurement property	Rating of measurement property	Quality of evidence
IIEF-15		
Structural validity	Inconsistent	Moderate
Internal consistency	Inconsistent	Moderate
Reliability	Inconsistent	Moderate
Measurement error	Indeterminate/Insufficient (Erectile Function subscale)	Very low
Construct validity	Inconsistent	Moderate
Criterion validity	Sufficient	High
Responsiveness	Sufficient	High
IIEF-5		
Structural validity	Sufficient	Moderate
Internal consistency	Indeterminate	
Reliability	Sufficient	Moderate
Measurement error	Indeterminate	
Construct validity	Sufficient	High
Criterion validity	Sufficient	Moderate
Responsiveness	Indeterminate	

DISCUSSION

This systematic review investigated the evidence regarding the measurement properties of the IIEF-15¹ and IIEF-5². In contrast to our hypothesis, most of the measurement properties were not rated as sufficient for both the IIEF-5 and IIEF-15. The IIEF-15 was rated as sufficient on criterion validity (of the Erectile Function subscale) and responsiveness, with sufficient ratings with high level of evidence. The evidence for structural validity, internal consistency, construct validity, and test-retest reliability were rated inconsistent, with moderate level of evidence. Measurement error for the Erectile Function subscale was rated as insufficient with very low quality of evidence, although it was indeterminate for the remaining subscales.

The IIEF-5 was rated as sufficient on criterion validity with high quality of evidence. The IIEF-5 was also rated as sufficient on structural validity, test-retest reliability, and construct validity, but with moderate quality of evidence because the evidence was based on very few studies. The evidence for internal consistency, measurement error, and responsiveness were rated as indeterminate.

With regard to structural validity, there is some evidence from CFAs^{28,36} and PCAs^{1,26} that the IIEF-15 consists of a 5-factor structure as hypothesized.¹ However, there is also evidence not supporting the 5-factor structure: 1 CFA found a poor fit for a 5-factor structure,¹⁷ 1 CFA found acceptable fits for both a 2-factor (1 factor of erectile function and orgasm, and 1 factor of desire and satisfaction) and 5-factor structure,³⁶ 1 CFA found acceptable fits for both a 4-factor (combined factor of erectile

function and intercourse satisfaction) and a 5-factor structure,²⁸ and multiple PCAs found either a 4-factor solution (combined component of erectile function and intercourse satisfaction,⁵¹ or combined component of intercourse satisfaction and overall satisfaction²²), or a 2-factor solution (1 component of erectile function and orgasm, and 1 component of desire and satisfaction,³⁶ or 1 component of sexual function and 1 component of sexual desire⁴³). There seems to be as much, if not more, evidence against the 5-factor structure.

The results of the current review are in line with the concerns raised by Forbes et al,^{52,53} that the 5-factor structure is not as firmly established as argued by Rosen et al.^{3,54} We agree with the reply by Rosen et al⁵⁴ that low correlations between subscales of the IIEF-15 do not warrant an insufficient rating of structural validity, but disagree with their underrating for the concerns regarding the structural validity of the IIEF-15. Their evidence cited concerns exploratory factor analyses, with no mention of confirmatory analyses that provide a higher level of evidence for structural validity. 2 of the confirmatory analyses we identified showed evidence for both the 5-factor structure and alternative factor structures,^{28,36} and the remaining CFA showed evidence against the 5-factor structure.¹⁷ Future studies are clearly needed to investigate alternative factor structures (eg, 2-factor, 4-factor, second-order hierarchical factors) and compare them directly to the posited 5-factor structure.

The structural validity of the IIEF-5 is also of interest. Whereas 1 Rasch analysis showed sufficient structural validity, no tests of unidimensionality were reported in any of the included articles. The IIEF-5 consists of items representing both erectile dysfunction (items 2, 4, 5, and 15 from the IIEF-15), as well as sexual intercourse satisfaction (item 7 from the IIEF-15). Theoretically, the IIEF-5 may be multidimensional due to the use of 2 constructs during development. Tests of unidimensionality are of importance to further determine the structural validity of the IIEF-5.

The internal consistency of the IIEF-15 showed values that were very high indicating possible redundancy ($\alpha > 0.95$; 3 studies of very good quality), as well as values considered too low ($\alpha < 0.70$; 1 study of very good quality). However, many studies (12 studies of inadequate to very good quality) showed sufficient internal consistency. The methodologic quality is of importance to put these values in context, where an equal number of very good-quality studies found insufficient as sufficient values. Considering these results, it is possible that internal consistency of the IIEF-15 may vary across subgroups. However, when examining the populations of the studies that reported sufficient values^{16,28,31,34–36,41,50} vs those of the studies that reported insufficient values,^{1,22,26,38,51} no clear pattern arose, with both groups of studies investigating different nationalities, as well as subgroups (eg, older men, HIV-positive men who have sex with men, sexually healthy men, men suffering from ED). Furthermore, these inconsistencies may be caused by differences in factor structure across subgroups. A future cross-cultural study design,

investigating measurement invariance, may help elucidate the inconsistencies of these findings.

The evidence on internal consistency of the IIEF-5 cannot yet be determined, because the unidimensionality (a prerequisite for internal consistency) has not yet been tested. However, if unidimensionality is tested and found to be sufficient, internal consistency is likely to be rated as sufficient. 1 study (of very good quality) found an insufficient value ($\alpha < 0.70$), whereas 3 studies of very good quality found sufficient values.

Although both the IIEF-15 Erectile Function subscale and the IIEF-5 were able to sufficiently predict ED diagnosis, it is not yet clear which cutoff scores are most suitable. Making a direct comparison between sensitivity and specificity ratings of cutoff scores across studies is beyond the scope of the current review, because an individual patient meta-analysis would be required. Furthermore, a larger sample (ie, more studies investigating criterion validity) would be necessary for such a meta-analysis to provide a reliable result. Further investigation into the criterion validity of the IIEF-15 and IIEF-5 is necessary for a more nuanced interpretation.

More information is necessary regarding the measurement error of both the IIEF-15 and the IIEF-5. Currently, the only available evidence is based on 1 study of inadequate quality.³⁵ This evidence showed an insufficient value for the Erectile Function subscale, but it is not possible to determine whether this is an artifact of the poor methodology of the study. Given the high frequency of use of both the IIEF-15 (particularly the Erectile Function subscale) and the IIEF-5 in clinical screening for ED, as well as outcome measures for clinical trials, knowledge on measurement error is important to be able to determine whether clinical change (ie, clinical improvement or deterioration) is a true change or is an artifact of the measurement tool itself. Fortunately, 1 study of very good quality calculated the MCID using multiple methods on a very large sample.³⁷ This information can be used to interpret any measurement error that is calculated for the Erectile Function subscale. We recommend researchers performing a test-retest reliability designed to calculate the LoAs or SDC, to further inform the field. More studies investigating the MCID are also necessary to further interpret measurement error.

A limitation of this review is that we did not investigate content validity. Content validity needs to be established before other measurement properties can be regarded.⁴ A future investigation of content validity is warranted. Another limitation of this review is the use of a precise rather than a sensitive search filter of measurement properties to identify studies to be included. The sensitivity of the precise filter was 93% in a random set of PubMed records, whereas the sensitivity of the sensitive search filter was 97%.⁹ The use of the precise filter was a pragmatic choice over the available sensitive filter because the initial search encompassed 39 PROMs (including the IIEF-15 and IIEF-5), and the sensitive filter would provide too many hits for feasible screening. The possibility remains that the precise filter missed validation studies of the IIEF-15 and IIEF-5.

In 2002, the IIEF-15 was considered to “meet psychometric criteria for test reliability and validity”.³ We offer a more cautious interpretation of the measurement properties of the IIEF-15. Although we support the claim that the IIEF-15 meets psychometric criteria for criterion validity (in regard to the Erectile Function subscale) and responsiveness; we argue that structural validity, internal consistency, test-retest reliability, construct validity, and measurement error have not yet been demonstrated to meet psychometric criteria. Given the widespread use of the IIEF-15 in both clinical practice and research, more thorough research is necessary regarding these measurement properties. A large-scale cross-cultural study design or an individual patient data meta-analysis, applying CFA, measurement invariance tests, internal consistency measures, and calculating the LoA or SDC, is recommended. It is possible that such research may suggest adjustments to be made to the IIEF-15 or its scoring.

The results of this review highlight a couple of important points for the interpretation of the IIEF-15 and IIEF-5 in clinical practice and research. First, some of the subscales may need to be combined, and interpreting them as 2 separate constructs may not be valid. Because the erectile function subscale is most often found in 1 factor with other subscales (based on both CFA and PCA), further research may find that other subscales should be combined with this subscale for a valid interpretation. Second, there is uncertainty what the optimal cutoff should be for the IIEF-15 and IIEF-5 to screen for ED, because multiple optimal cutoff scores were reported for both the IIEF-15 and IIEF-5. Further research is necessary to investigate optimal cutoff points. For current practice, it is important that researchers and clinicians maintain consistency, and, as such, the cutoff points of 25 for the IIEF-15 EF domain and 21 for the IIEF-5 should be maintained. We do suggest that researchers and clinicians keep a close eye on further research of criterion validity, because another cutoff point may prove to be more accurate. Third and last, the lack of information on measurement error is a problem for the interpretation of change scores of the IIEF-15 and IIEF-5. We advise using the IIEF in tandem with another measure when determining ED development in patients, because this may lead to a more robust interpretation of change over time.

CONCLUSION

The IIEF-15 meets psychometric criteria for criterion validity (with regard to the Erectile Function subscale) and responsiveness; but structural validity, internal consistency, test-retest reliability, construct validity, and measurement error have not yet been demonstrated to meet psychometric criteria. In particular, further research into the structural validity of the IIEF-15 is of relevance. The IIEF-5 meets psychometric criteria for structural validity, test-retest reliability, construct validity, and criterion validity. Internal consistency, measurement error, and responsiveness require further research. The most pressing matter for future research is determining the unidimensionality of the IIEF-5.

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SUPPLEMENTARY DATA

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jsxm.2019.04.010>.